



NSW  
Therapeutic  
Advisory  
Group Inc.

Advancing  
quality use  
of medicines  
in NSW

## TAG Mail: January to February 2024 Cumulative Listing of Reports, Publications, Medication Safety

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### Fortnightly TAG Mail – resources list      1 February 2024

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We're piloting a new feature in TAGMail 2024- Editor's Picks- for those short on time!

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#### NSW TAG ACTIVITIES

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##### Current open email discussions

##### 1. Long-term supply issue with lidocaine 2% + 1:200,000 adrenaline injection

A NSW TAG member has the following query regarding the long-term supply of lidocaine 2% + 1:200,000 adrenaline injection. They are looking to benchmark their practice with other LHDs.

How is your hospital/district managing the supply issue:

- compounding or obtaining 3<sup>rd</sup> party compounded product,
- using an alternative, such as ropivacaine 0.75%,
- supplying drugs separately and anaesthetists mixing as needed in theatres, or
- doing something else? Closes **15<sup>th</sup> February 2024**.

##### 2. Storage of medicines in patient's locked drawers and medication transfer between treatment room and bedside

'Following recent DTC accreditation, one of the accreditors questioned strips of medications, rather than original boxes, being in the locked patient bedside drawers and also how medications are transported from the treatment room to the patient bedside, again original packaging vs strips.

What are other hospitals doing in terms of keeping strips of medications in patient's drawers? These would be medications that are on ward imprest, kept within their original packaging in the treatment room but a strip may be placed in the patient's locked drawer, e.g. paracetamol. And following on from that, do nursing staff take medications in original packaging from the treatment room to the patient bedside or would they just take strips of medication? The Medication Handling policy mentions supply of medications from pharmacy in original packaging, unless dispensed for specific patients, but not specifically storage on the wards.' Closes **15<sup>th</sup> February 2024**

##### Upcoming TAG meeting dates

NSW Management Committee 21<sup>st</sup> February 2024

Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions or upcoming meetings.

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#### EDITOR'S PICKS

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**British Medical Journal (BMJ):** Reducing patient and planetary harms from high anticholinergic burden medication – [link](#) – [SPS commentary](#)

**BMJ Open:** Availability of evidence and comparative effectiveness for surgical versus drug interventions: an overview of systematic reviews and meta-analyses - [link](#)

**Diabetes Care:** The Specialist Treatment of Inpatients: Caring for Diabetes in Surgery (STOIC-D Surgery) Trial: A Randomized Controlled Trial of Early Intervention With an Electronic Specialist-Led Model of Diabetes Care – [link](#) – [SPS commentary](#)

**European Heart Journal:** The '10 commandments' for the 2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes - [link](#)

**Heart:** - Cardiogeriatrics: the current state of the art - [link](#)

**International Journal for Quality in Health Care:** Monitoring for adverse drug events of high-risk medications with a computerized clinical decision support system: a prospective cohort study - [link](#)  
**Journal of the American College of Cardiology:** When Direct Oral Anticoagulants Should Not Be Standard Treatment: JACC State-of-the-Art Review - [link](#)  
**UK Clinical Pharmacy Association:** Joint Position Statement between UK Clinical Pharmacy Association and the Royal College of Emergency Medicine regarding Pharmacists & Pharmacy Services in Emergency Departments - [link](#)

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## **OTHER NEWS (new additions in bold)**

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### **NSW Health**

- Measles alert for Sydney International Airport [[24 January 2024](#)]
- Public health warning: tablets sold as MDMA (Ecstasy) found to contain a potent opioid [[29 January 2024](#)]
- Public Health Emergency Response Preparedness ([PD2024\\_002](#)) [23 January 2024]

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## **REPORTS AND PUBLICATIONS – AUSTRALIA**

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### **Agency for Clinical Innovation, NSW (ACI)**

The latest weekly Evidence Digest can be found [here](#)

### **Australian Government Department of Health**

- Shield yourself from shingles – Resources collection - [link](#)

### **Australian Institute for Health and Welfare (AIHW)**

- Australia's disability strategy update & annual report - [link](#)
- Specialist paediatric palliative care delivered to children who died in 2021 - [link](#)
- Aboriginal and Torres Strait Islander specific primary health care: results from the OSR and nKPI collections - [link](#)
- Medicare Benefits Scheme funded services: monthly data - [link](#)

### **MIMS monthly updates – February 2024**

- New Products
  - Tebentafusp ([Kimmtrak](#)) is a bispecific fusion protein, comprised of a T cell receptor (TCR) fused to an antibody fragment with specificity for the CD3 (cluster of differentiation 3) receptor, found on polyclonal T cells. The TCR has specificity for a gp100 peptide (expressed preferentially in melanoma cells) presented by human leukocyte antigen-A\*02:01 (HLA-A\*02:01). In vitro, tebentafusp bound to HLA-A\*02:01-positive uveal melanoma cells and activated polyclonal T cells to release inflammatory cytokines and cytolytic proteins, which results in direct lysis of uveal melanoma tumour cells. Kimmtrak is indicated for the treatment of HLA-A\*02:01-positive adult patients with unresectable or metastatic uveal melanoma. Kimmtrak concentrate for intravenous infusion contains tebentafusp 0.1 mg per 0.5 mL and is available in packs of 1 vial
- New indications
  - [Raxtozinameran](#) (Comirnaty Omicron XBB.1.5) is now indicated for active immunisation to prevent COVID-19 in individuals 6 months of age and older in accordance with official recommendations
  - Tozinameran and famtozinameran ([Comirnaty Original/Omicron BA.4-5](#)) is now indicated (with provisional approval) for active immunisation to prevent COVID-19 in individuals 5 years of age and older in accordance with official recommendations
  - Vosoritide ([Voxzogo](#)) is now indicated for the treatment of achondroplasia in all paediatric patients whose epiphyses are not closed

### **PBS**

- PBS Website Update - [1 February 2024](#)

### **TGA**

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- Iomustine [10mg 40mg](#) ; lisdexamfetamine dimesylate [50mg 60mg](#) ; midodrine [50mg](#)

- AusPARs:
  - Sunlenca ([Lenacapavir sodium](#)) for the treatment of adults with multidrug resistant HIV 1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen
  - Retevmo ([selpercatinib](#)) is provisionally approved for treatment of adults with locally advanced or metastatic RET fusion positive non-small cell lung cancer
- Australian prescription medicine decision summaries:
  - [Arexvy](#) (recombinant respiratory syncytial virus pre-fusion F protein) is approved for individuals 60 years and older for prevention of lower respiratory tract disease caused by respiratory syncytial virus
  - Wezlana ([ustekinumab](#)) for plaque psoriasis, psoriatic arthritis, Crohn's, ulcerative colitis

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## REPORTS AND PUBLICATIONS – INTERNATIONAL

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### Canadian Agency for Drugs and Technologies in Health

- Health Technology Review Updates: Biologic Drugs for Severe Asthma - [link](#) ; Buprenorphine Formulations for Opioid Use Disorder – [link](#) ; The Safety of Niraparib in Ovarian Cancer – [link](#) ; Ketamine for Adults With Treatment-Resistant Depression or Posttraumatic Stress Disorder: A 2023 Update – [link](#) ; Ketorolac for Renal Colic - [link](#)

### Department of Health and Social Care UK

- Improving the mental health of babies, children and young people (BCYP) - [link](#)
- Expanding access to naloxone: Final outcome – [link](#) – [SPS commentary](#)

### electronic Medicines Compendium (eMC) (UK)

- [New products](#)
- BCG-medac Powder and solvent for intravesical suspension for carcinoma-in-situ of the urinary bladder, prevention of recurrence of high-risk non-muscle invasive urothelial bladder carcinoma after resection, and treatment/ prevention of recurrence of aggressive variants of urothelial carcinoma
- Bekemv (eculizumab)- biosimilar to Soliris for use in adults and children for paroxysmal nocturnal haemoglobinuria and atypical haemolytic uraemic syndrome – [SPS commentary](#)
- Camzyos (mavacamten)- selective, allosteric, and reversible cardiac myosin inhibitor for symptomatic adult obstructive hypertrophic cardiomyopathy
- Ebglyss (lebrikizumab) immunoglobulin (IgG4) monoclonal antibody that binds with high affinity to interleukin-13, licensed for moderate-to-severe atopic dermatitis in adults and adolescents ≥12 years of age of at least 40 kg who are candidates for systemic therapy
- Elrexfio (elranatamab)- bi-specific T-cell engaging antibody licensed as monotherapy in adults with relapsed & refractory multiple myeloma, who have received ≥3 prior therapies, including immunomodulatory agent, proteasome inhibitor & anti-CD38 antibody, with disease progression on last therapy
- Evkeeza (evinacumab), a recombinant human monoclonal antibody, which specifically binds to and inhibits ANGPTL3, for use as an adjunct to diet and other LDL-C lowering therapies for the treatment of adults and adolescents aged ≥12 years with homozygous familial hypercholesterolaemia
- Eylea (aflibercept) for wet age-related macular degeneration (AMD) and visual impairment due to diabetic macular oedema (DMO). Each vial contains 0.263ml, providing an 8mg dose to be given monthly for 3 doses for AMD and DMO. Dosing interval may be extended for up to 4 months
- Korserdu (elacestrant)- oral oestrogen receptor-α antagonist & degrader for use in postmenopausal women/men with ER+ve, HER2-ve locally advanced/metastatic breast cancer with an activating ESR1 mutation & disease progression after first line endocrine therapy including CDK 4/6 inhibitor
- Levorol (levomepromazine maleate) psychiatric conditions, e.g. schizophrenia, as alternative to chlorpromazine particularly to reduce psychomotor activity. Also, as an adjunct in terminal illness for the relief of pain, distress and refractory (non-chemotherapy related) nausea
- Loargys (pegzilarginase) a cobalt substituted recombinant human arginase 1 enzyme conjugated with a mPEG carrier for arginase 1 deficiency (hyperargininemia) in adults, adolescents and children aged 2 years and older
- Opdualag (nivolumab, relatlimab)- fixed dose combination of nivolumab (anti-PD-1) and relatlimab (anti-LAG-3) for the first line treatment of advanced (unresectable or metastatic) melanoma in adults & adolescents 12 years of age and older

- Quviviq (daridorexant) licensed for adult insomnia characterised by symptoms present for at least 3 months & considerable impact on daytime functioning – [SPS commentary](#)
- Sildenafil KRKA 100mg orodispersible tablets for the treatment of adult men with erectile dysfunction, are an alternative option for patients who have difficulty swallowing film-coated tablets.
- Strigol (macrogol 3350) Paediatric 6.86 g powder for oral solution – Lemon - each sachet contains macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride for chronic constipation and prevent re-impaction after successful disimpaction in children 2-11 years old and to treat faecal impaction in children aged ≥ 5 years
- New indications/extensions
- Keytruda (pembrolizumab) - as monotherapy for the adjuvant treatment of adults with non-small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum based chemotherapy
- Mircera (methoxy polyethylene glycol-epoetin beta) - extension to cover treatment of symptomatic anaemia linked to chronic kidney disease in paediatric patients from 3 months to <18 years of age who are converting from another erythropoiesis stimulating agent (ESA) after haemoglobin stabilised with previous ESA
- Mirena (levonorgestrel) - duration of use extended to 8 years for contraception, and 5 years in induction of idiopathic menorrhagia.
- Opdivo (nivolumab) - adolescent melanoma indication (from age 12 years), and its related dosing

### European Medicines Agency (EMA)

- EMA Human medicines highlights 2023 - [link](#)
- EMA confirms recommendation for non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna - [link](#)

### Food and Drug Administration (FDA) USA

- FDA revises letter of authorization for the emergency use authorization for Paxlovid - [link](#)
- New Drug approvals
- erdafitinib for locally advanced or metastatic urothelial carcinoma - [link](#)
- ceftazidime/avibactam ([Avycaz](#)) - all indications approved for newborns of at least 31 weeks gestational age
- pembrolizumab ([Keytruda](#)) for hepatocellular carcinoma secondary to hepatitis B
- immune globulin IV ([Gammagard Liquid](#)) for chronic inflammatory demyelinating polyneuropathy
- dupilumab ([Dupixent](#)) for eosinophilic esophagitis expanded to include children aged 1 y and older who weigh at least 15 kg
- bupivacaine/meloxicam ([Zynrelef](#)) for soft tissue and orthopedic surgical procedures including foot and ankle expanded
- immune globulin SC ([HyQvia](#)) for chronic inflammatory demyelinating polyneuropathy

### General Pharmaceutical Council

- Joint statement on meeting regulatory standards during periods of global or national shortage of medicines – an update - [link](#)

### House of Commons Science and Technology Committee

- The antimicrobial potential of bacteriophages - [link](#)

### Medicines and Healthcare products Regulatory Agency (MHRA)

- Regulatory Roadmap published for new measures to support safe access to medical technology including AI and diagnostics - [link](#)
- Omijara licensed for anaemic myelofibrosis patients to treat the symptoms of their disease - [link](#)
- Rezzayo approved to treat adult patients with invasive candidiasis - [link](#)
- MHRA approves four-dose [Mounjaro](#) (tirzepatide) KwikPen for diabetes and weight management

### Monthly Index of Medical Specialities MIMS UK

- Mirena levonorgestrel-releasing intrauterine system (IUS) licensed for longer use - [link](#)

### **NHS England**

- Improving the physical health of people living with severe mental illness – [link](#) – [SPS commentary](#)
- Five key elements for discharge – supporting people with a learning disability and autistic people to leave hospital - [link](#)
- Guidance for risk assessment and infection prevention and control measures for measles in healthcare settings – [link](#) – [SPS commentary](#)
- Direct-to-consumer point-of-care in vitro diagnostic devices for group A streptococcal infections - [link](#)
- Blood matching genetic test to be made available on the NHS for patients with sickle cell disorder and thalassaemia to reduce transfusion side effects - [link](#)

### **NHS Scotland (Scottish Medicines Consortium)**

- Accepted for use:
  - [Burosumab](#) (Crysvita®) for X-linked hypophosphataemia
  - [Pembrolizumab](#) (Keytruda®) for microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) tumours
- Not recommended:
  - [Belantamab mafodotin](#) (Blenrep®) for multiple myeloma

### **National Institute for Health and Care Excellence (NICE) UK**

- Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer ([TA946](#))
- Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments ([TA947](#))
- Ivosidenib for treating advanced cholangiocarcinoma with an IDH1 R132 mutation after 1 or more systemic treatments ([TA948](#))
- Updated NICE guidance recommends more targeting of antibiotics to those at the highest risk of suspected sepsis - [link](#)
- Other updates: Neonatal infection ([QS75](#)) ; Skin cancer ([QS130](#))

### **National Institute for Health and Care Research (NIHR)**

- NIHR Alert: How to improve investigations of medical harm - [link](#)

### **Obesity Action Coalition**

- Joint statement calls on the US FDA to stipulate that people with obesity must be included in drug trials - [link](#)

### **Royal Pharmaceutical Society**

- Royal Pharmaceutical Society revises position on prescribing and dispensing by same healthcare professional – [link](#) – [SPS commentary](#) – [position statement](#) – [SPS commentary](#)

### **Specialist Pharmacy Services NHS UK**

- Use of nefopam for chronic pain - [link](#)
- Natalizumab biosimilar: Patient Information Sheet - [link](#)
- Treating herpes virus infections during breastfeeding - [link](#)

### **The Queen's Nursing Institute**

- 70 years of end of life care in the community - [link](#)

### **UK Clinical Pharmacy Association**

- Joint Position Statement between UK Clinical Pharmacy Association and the Royal College of Emergency Medicine regarding Pharmacists & Pharmacy Services in Emergency Departments - [link](#)

### **World Health Organisation (WHO)**

- Guidelines on the Clinical Management of Sepsis - [link](#)

- World Health Organisation (WHO) warns of alarming 45-fold rise in measles in Europe - [link](#) – [SPS commentary](#)
- WHO awards countries for progress in eliminating industrially produced trans fats for first time - [link](#)
- Shortages impacting access to glucagon-like peptide 1 receptor agonist products; increasing the potential for falsified versions - [link](#)

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## MEDICATION SAFETY

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### British National Formulary

- Pharmacodynamic effects tables now in digital formats - [link](#)

### electronic Medicines Compendium (eMC) (UK)

#### - [Revised SPCs](#)

- Avelox (moxifloxacin), Ciproxin (ciprofloxacin) - possible risk of prolonged, disabling and potentially irreversible serious ADRs highlighted
- Buccolam (midazolam) - anaphylactic reaction (unknown frequency) added as ADR
- Cabometyx (cabozantinib) - pneumonia added as one of the most common serious ADRs in both renal cell carcinoma and differentiated thyroid carcinoma
- Cetirizine hydrochloride products- contraindication in patients with end-stage renal disease (GFR < 15 ml/min) and dosing information in renal impairment. Breast-feeding risk information and myalgia ADR of unknown frequency added
- CitraFleet (light magnesium oxide, sodium picosulfate, citric acid) - may induce aphthoid ulcers of the colonic mucosa, with reports of serious cases of colitis (including ischaemic colitis). Colitis should be considered in cases of severe and/or persistent abdominal pain, with/without rectal bleeding, after the ingestion of CitraFleet
- Doxorubicin Baxter - interstitial lung disease, which may have an acute onset, observed in patients receiving pegylated liposomal doxorubicin, including fatal cases
- Eliquis (apixaban) - anticoagulant-related nephropathy (ARN) added as ADR (frequency unknown). In patients with kidney disease, it may occur, possibly in relation to episodes of excessive anticoagulation and haematuria. Consider possibility of haemorrhage if evaluating the condition
- Elvanse (lisdexamfetamine) Hard Capsules – adult indication (use as part of a comprehensive treatment programme for ADHD in adults with pre-existing symptoms of ADHD in childhood), has been incorporated into the Elvanse SmPCs which previously only included paediatric indication
- Epilim (sodium valproate) products - new safety measures to reduce the known harms of valproate, including risk of birth defects and neurodevelopmental disorders following use in pregnancy, and the risk of impaired fertility in males – [SPS commentary](#)
- Epistatus (midazolam) - anaphylactic reaction added as possible ADR of unknown frequency (SPC notes added because this has been reported to occur when midazolam is injected in children and/or adults, which may be of relevance to oromucosal administration)
- Erleada (apalutamide) - risk of interstitial lung disease, including fatalities. Should be interrupted if there is acute onset &/or unexplained worsening of pulmonary symptoms, & if confirmed, it should be discontinued. Restless leg syndrome added as uncommon ADR
- Esmeron (rocuronium bromide) - mydriasis and fixed pupils as ADRs, in the context of a potential increased permeability or compromise of the integrity of the blood-brain barrier
- Eumovate (clobetasone butyrate) - long term topical steroids use can result in the development of rebound eczema and dermatitis flares after stopping treatment (topical steroid withdrawal syndrome)
- Hydrocortisone creams & ointment - hydrocortisone 1% is classed as a mild corticosteroid – [SPS commentary](#)
- Kivexa (lamivudine, abacavir sulfate) - increased risk of cardiovascular events (notably myocardial infarction). It advises that action be taken to minimise modifiable risk factors (e.g. smoking) and to consider alternative treatment options for those with high cardiovascular risk
- Inovelon (rufinamide) - change in excipients, including information about sorbitol, benzoic acid and sodium content
- Kisplyx Lenvima (lenvatinib mesilate) - adrenal insufficiency added as possible ADR, frequency 'uncommon' for monotherapy and in combination with everolimus, and 'common' in combination with pembrolizumab

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Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

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An initiative of NSW clinical pharmacologists & pharmacists

ABN: 82 707 308 091

- Lokelma (sodium zirconium cyclosilicate) - constipation added as a common ADR
- Lorviqua (lorlatinib) - proteinuria added as a common ADR. The frequency is 3.4% for all grades and 0.4% for grade 3-4, which represents a more serious adverse effect
- Lyrica (pregabalin) - suicidal ideation added as a rare ADR
- Lyxumia (lixisenatide) - cholelithiasis and cholecystitis added as uncommon ADRs. The word "before" added to line in interaction section on administration of oral contraceptive "1 hour" before or 4 hours after lixisenatide did not affect AUC & t1/2 of ethinylestradiol and levonorgestrel
- Mirapexin (Pramipexole) - restless legs augmentation syndrome (earlier onset of symptoms in the evening/afternoon, increase in symptoms, and involvement of other extremities) added as very common ADR. If suspected, use lowest effective dose, or consider stopping treatment
- Mirena (levonorgestrel) - Updated information on risk in post-menopausal women, adverse reactions, and bleeding patterns also added
- Movicol (macrogol 3350) - warning that medicines in solid dose form taken within 1 hour of large volumes of Movicol may be flushed from the gastrointestinal tract and not absorbed
- Nortriptyline - high doses in late pregnancy may cause lethargy in the newborn and urinary retention in pregnant women. Serotonin syndrome has been added as an ADR of unknown frequency. Additionally, several years of treatment may be needed for recurrent depression
- Norvir (ritonavir) - piroxicam removed from the contraindications and interactions sections
- Otrivine (xylometazoline) - use with caution in patients taking tri or tetra-cyclic antidepressant treatment, as concomitant use may cause an increase in blood pressure due to the cardiovascular effects of these substances
- Premarin (conjugated oestrogens) - interaction of oestrogens with lamotrigine. Contraceptives containing oestrogens have been shown to reduce lamotrigine plasma concentrations due to induction of lamotrigine glucuronidation. It is expected that a similar interaction exists with HRT
- Paxlovid (nirmatrelvir, ritonavir) - Stevens-Johnson syndrome, toxic epidermal necrolysis & anaphylaxis added as rare ADR; hypertension as an uncommon ADR. Potential for increased verapamil, calcineurin inhibitor & mTOR inhibitor levels with concomitant Paxlovid noted, and related monitoring advice included
- Prezista (darunavir) - crystal nephropathy as a rare ADR identified in the post-marketing setting
- Resonium A (sodium polystyrene sulfonate) - risk of severe gastrointestinal disorders (such as bowel obstruction, ischaemia, necrosis or perforation) so use of polystyrene sulfonate is not recommended in patients with compromised gastrointestinal motility
- Rinvoq (upadacitinib hemihydrate)- hypoglycaemia in patients treated for diabetes added as a precaution. Dose adjustment of anti-diabetic medication may be necessary if hypoglycaemia occurs
- Rivastigmine Dr. Reddys - risk of electrocardiogram QT prolongation warning. Caution is advised in patients with pre-existing/family history of QTc prolongation or at higher risk of developing torsade de pointes. ECG monitoring may be required for some people
- Rybelsus (semaglutide) - dizziness added as a new common ADR
- Salofalk (mesalazine) - treatment should be stopped if renal function deteriorates, warnings on serious blood dyscrasias and cardiac hypersensitivity reactions (myocarditis and pericarditis), rash and pruritis added as common ADRs
- Sancuso (granisetron) patch - may mask progressive ileus and gastric distension. Serotonin syndrome and skin reactions added as ADRs of unknown frequency. Buprenorphine and opioids now listed as medicines that may lead to serotonin syndrome, when used with granisetron
- Sandrena (estradiol hemihydrate) - oestrogen containing contraceptives significantly decrease concentrations of lamotrigine when used together. Although this interaction with HRT and lamotrigine not studied, similar effects expected, leading to reduced seizure control
- Sevoflurane Baxter - delirium has been added as ADR of unknown frequency
- Shingrix Herpes zoster vaccine (recombinant, adjuvanted) - can be given concomitantly with any authorised or approved COVID-19 mRNA vaccine. This is based on data from the ZOSTER-091 study
- Spikevax (formerly COVID-19 Vaccine Moderna) XBB.1.5 vaccine - warning about use in immunocompromised individuals removed, safety data in organ transplant recipients and immunogenicity data in organ transplant recipients included

- Tecentriq (atezolizumab) - data from phase 3 IMvigor130 trial of atezolizumab as monotherapy and in combination with platinum-based chemotherapy in patients with untreated locally advanced or metastatic urothelial carcinoma added
- Tecvayli (teclistamab) – recommendation to reduce the dosing frequency to 1.5 mg/kg by subcutaneous injection every two weeks for patients who have a complete response or better for a minimum of 6 months
- Tegretol (carbamazepine) - hypersensitivity reaction information added to advise class I (immediate) reactions including rash, pruritus, urticaria, angioedema & anaphylaxis have been reported, and treatment must be discontinued if they occur. Loratadine removed from list of interacting medicines
- Tobramycin - increased risk of ototoxicity in mitochondrial DNA mutations (particularly nucleotide 1555 A to G substitution in 12S rRNA gene), even if serum levels are within the recommended range during treatment. Alternative options should be considered in such patients
- Vabysmo (faricimab) injection - rare cases of retinal vasculitis and/or retinal occlusive vasculitis spontaneously reported in post-marketing and in patients treated with intravitreal therapies
- Varivax (varicella-zoster virus [live] vaccine) - syncope as post-marketing surveillance ADR
- Verzenios (abemaciclib) - potential increased risk for serious arterial thromboembolic events (ATEs), including an ischaemic stroke and MI when administered with endocrine therapies. Benefits and risks of continuing abemaciclib in those who experience serious ATE should be considered
- Veyvondi (vonicipog alfa) - co-administration of von Willebrand factor and factor VIII, (including pre-mixing these in a single syringe) information removed. Dosing information for long-term prophylaxis against bleeds in von Willebrand disease added
- Vfend (voriconazole) - newly calculated frequencies for following ADRs: squamous cell carcinoma (SCC) of skin (including cutaneous SCC in situ or Bowen's disease) from "not known" to "common", phototoxicity from "uncommon" to "common", and periostitis from "not known" to "uncommon."
- Xifaxanta (rifaximin) - severe cutaneous adverse reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis reported in association with use of rifaximin in patients with cirrhosis
- Yasmin (ethinylestradiol, drospirenone) - exogenous oestrogens may induce or exacerbate symptoms of acquired (as well as hereditary) angioedema. This ADR has an unknown frequency
- Zavesca (miglustat) - Crohn's disease diagnosed in patients with Niemann-Pick type C disease who are taking miglustat. In patients with chronic diarrhoea and/or abdominal pain that worsen or do not respond to treatment, the possibility of Crohn's disease should be considered
- Zejula (niraparib tosylate monohydrate) - myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML) added as common ADRs. Patients with suspected AML/MDS should be referred to a haematologist. Contraceptive advice in women of childbearing age has changed from use for 1 month to 6 months after the last dose
- Ziagen (abacavir sulfate) - increased risk of cardiovascular events (notably myocardial infarction). Action should be taken to minimise modifiable risk factors (e.g. smoking) and to consider alternative treatment options for those with high cardiovascular risk
- Risk minimisation materials
- Abstral (fentanyl citrate) sublingual tablets. The prescriber's guide contains information on breakthrough pain, administration, titration, side-effects, switching and stopping treatment, breastfeeding, and provision of guidance to patients/carers. A patient/carer guide is also available
- Casgevy (exagamglogene autotemcel) Patient/carer guide contains information on the possibility of neutrophil engraftment failure (with associated increased risk of infections) and longer time to platelet engraftment (increased risk of bleeding). A patient alert card and administration guide also available
- eculizumab (Bekemv) Materials include a Physician's Guide, discussing risk of severe infection and sepsis, especially meningococcal infection, signs and symptoms of severe infection, how to minimise this risk (vaccination requirements; antibiotic prophylaxis) and other serious ADRs – [SPS commentary](#)
- Elrexfio (elranatamab) patient alert card. This patient card, which should be carried at all times, includes information on symptoms of cytokine release syndrome and neurological toxicity, including immune effector cell associated neurotoxicity syndrome, which may be fatal or life-threatening
- etranacogene dezaparvovec (Hemgenix) Materials include a healthcare professional guide discussing important risks related to this treatment (hepatotoxicity; thromboembolism; malignancy);



germline and horizontal transmission; development of factor IX inhibitors) and how to minimise these  
– [SPS commentary](#)

- Litlecitol (ritlecitinib) - Prescriber guide provides a checklist for assessments prior to prescribing, management, monitoring and safety considerations related to the Risk Management Plan for ritlecitinib. A Patient Card containing information on important side-effects is also available
- Opdulag (nivolumab and relatlimab) patient card. This medicine can cause serious immune-mediated side-effects that can affect different parts of the body. This card, which must be carried with the person being treated at all times, lists the side effects that can be life threatening and need to be addressed immediately
- PecFent (fentanyl citrate) nasal spray. A prescribers guide containing important information on its safe prescribing and use discusses dosing and titration, overdose, opioid use disorder, and includes a prescribers checklist. There is also a pharmacist's guide to dispensing and a patient/carer guide
- Zynlonta (loncastuximab tesirine) Patient Card with important safety information, including risk of photosensitivity reactions, such as sunburn-like reactions following exposure to light, itchy rash, skin blistering, darker skin patches, irritation, swelling & pain

### **EMA**

- Precautionary measures to address potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines - [link](#)
- EMA confirms measures to minimise the risk of serious side effects with medicines containing pseudoephedrine - [link](#)

### **Food and Drug Administration (FDA) USA**

- FDA adds Boxed Warning for increased risk of severe hypocalcaemia in patients with advanced chronic kidney disease taking denosumab (Prolia) – [link](#) – [SPS commentary](#)

### **Health Canada – MedEffect Notice**

- Health Product InfoWatch, [January 2024](#)

### **Institute for Safe Medication Practices (ISMP) USA**

- Medication Safety Alert! [January 25, 2024](#)
- Be Wary of Controlled and Non-Controlled Medication Replicas Sold Online - [link](#)

### **Medicines and Healthcare products Regulatory Agency (MHRA) UK**

- Drug Safety Update, [January 2024](#)
- Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate - [link](#) – [SPS commentary](#)
- Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors - [link](#)
- Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell ▼): new safety and educational materials to support regulatory measures in men and women under 55 years of age - [link](#) – [SPS commentary](#)
- New valproate safety measures apply from 31 January - [link](#)

### **Medsafe (New Zealand Medicines and Medical Devices Safety Authority)**

- Medsafe successfully prosecutes seller of fake "Miracle Cure" - [link](#)

### **MIMS monthly updates – [February 2024](#)**

- New contraindications
- Iopromide ([Ultravist](#) 300 and 370) now contraindicated for intrathecal use
- Metoclopramide hydrochloride ([Maxolon](#)) tablets now contraindicated in children below 15 years
- Rifabutin ([Mycobutin](#)) is now contraindicated for concomitant use with rilpivirine prolonged-release suspension for injection

### **Specialist Pharmacy Service**

- Understanding drug interactions - [link](#)
- Using heparins during breastfeeding - [link](#)

### **TGA**

- Product Information safety updates - [January 2024](#)
- Nitrosamine impurities acceptable intakes update - [link](#)
- The following pose a serious risk to health and should not be taken: [Artri King tablets](#); [Commander Stamina Time tablets](#); [Throb Herbal supplement tablets](#); [Kamasutra herbal jelly for him bottle](#); [Excite for her tablets](#); [Kamasutra Herbal Jelly for him oral jelly sachets](#)

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### **PAPERS OF INTEREST**

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#### **American Journal of Cardiology**

- Early Initiation of PCSK9 Inhibitor Therapy Versus Placebo in Patients With Acute Coronary Syndrome: A Systematic Review and Meta-Analysis - [link](#)

#### **American Journal of Gastroenterology**

- Antibiotics with or without rifaximin for acute hepatic encephalopathy (HE) in critically ill patients With cirrhosis: A double-blind, randomized controlled (ARiE) trial - [link](#)

#### **American Journal of Health-System Pharmacy (AJHP)**

- Tenecteplase-associated orolingual angioedema: A case report and literature review - [link](#)
- Risk of bleeding with concomitant use of oral anticoagulants and aspirin: A systematic review and meta-analysis - [link](#)
- Implementation of clopidogrel pharmacogenetic clinical decision support for a preemptive return of results program - [link](#)
- Implementation of vancomycin AUC/MIC dosing vs traditional trough dosing and incidence of acute kidney injury at a rural community hospital - [link](#)

#### **Annals of Internal Medicine**

- Effectiveness of Recombinant Zoster Vaccine Against Herpes Zoster in a Real-World Setting – [link](#) – [SPS commentary](#)
- Effectiveness of Existing Insomnia Therapies for Patients Undergoing Hemodialysis: A Randomized Clinical Trial - [link](#)
- Gabapentinoids and Risk for Severe Exacerbation in Chronic Obstructive Pulmonary Disease: A Population-Based Cohort Study - [link](#)
- Talking With Patients About the New Anti-amyloid Alzheimer Disease Medications - [link](#)

#### **Arthritis & Rheumatology**

- Clinical characteristics of cryopyrin-associated periodic syndrome and long-term real-world efficacy and tolerability of canakinumab in Japan: results of a nationwide survey - [link](#)

#### **British Journal of Clinical Pharmacology**

- Gabapentinoids in Ireland 2010 to 2020: An observational study of trends in gabapentinoid prescribing, law enforcement drug seizures and post-mortem toxicology - [link](#)
- Observational studies to emulate randomized trials: Some real-world barriers - [link](#)
- A physiological approach to renal clearance: From premature neonates to adults - [link](#)

#### **British Journal of General Practice**

- Cost-utility analysis of molnupiravir plus usual care versus usual care alone as early treatment for community-based adults with COVID-19 and increased risk of adverse outcomes in the UK PANORAMIC trial - [link](#)

#### **British Journal of Psychiatry**

- Sensitivity to light in bipolar disorder: implications for research and clinical practice - [link](#)

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Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

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An initiative of NSW clinical pharmacologists & pharmacists

ABN: 82 707 308 091

### **British Medical Journal (BMJ)**

- Combining high quality data with rigorous methods: emulation of a target trial using electronic health records and a nested case-control design - [link](#)
- Efficacy and safety of tranexamic acid in acute haemorrhage - [link](#)
- Improving the transparency and reliability of observational studies through registration - [link](#)
- Why learning how to swallow pills is good for patients, parents, and the planet - [link](#)
- Effect of Risk Mitigation Guidance opioid and stimulant dispensations on mortality and acute care visits during dual public health emergencies: retrospective cohort study – [link](#) – [SPS commentary](#)
- Undisclosed financial conflicts of interest in DSM-5-TR: cross sectional analysis – [link](#) – [SPS commentary](#)
- Perinatal depression and its health impact – [link](#) – [SPS commentary](#)
- Inclisiran: the test case drug for the Government's life sciences strategy - [link](#)
- Anaemia Management in Chronic Kidney Disease - [link](#)
- Reducing patient and planetary harms from high anticholinergic burden medication – [link](#) – [SPS commentary](#)
- Therapeutic advances in rheumatoid arthritis - [link](#)

### **BMJ Open**

- Cannabis for medical use versus opioids for chronic non-cancer pain: a systematic review and network meta-analysis of randomised clinical trials - [link](#)
- NSAID prescribing and adverse outcomes in common infections: a population-based cohort study - [link](#)
- Availability of evidence and comparative effectiveness for surgical versus drug interventions: an overview of systematic reviews and meta-analyses - [link](#)
- Role of vitamin D supplementation in modifying outcomes after surgery: a systematic review of randomised controlled trials - [link](#)
- Association between antidepressant use during pregnancy and miscarriage: a systematic review and meta-analysis – [link](#) – [SPS commentary](#)

### **Circulation**

- Efficacy and Safety of Non-Vitamin-K Antagonist Oral Anticoagulants Versus Warfarin Across the Spectrum of Body Mass Index and Body Weight: An Individual Patient Data Meta-Analysis of Four Randomized Clinical Trials of 58 464 Patients With Atrial Fibrillation - [link](#)

### **Cochrane**

- Deep neuromuscular blockade in adults undergoing an abdominal laparoscopic procedure - [link](#)
- Early versus late administration of amino acids in preterm infants receiving parenteral nutrition - [link](#)
- Non-vitamin-K-antagonist oral anticoagulants (NOACs) after acute myocardial infarction: a network meta-analysis - [link](#)
- Probiotics for the postoperative management of term neonates after gastrointestinal surgery - [link](#)

### **Diabetes Care**

- Impact of Glucose-Lowering Medications on Health-Related Quality of Life in Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE) - [link](#)
- Comparative Effects of Randomized Second-line Therapy for Type 2 Diabetes on a Composite Outcome Incorporating Glycemic Control, Body Weight, and Hypoglycemia: An Analysis of Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE) - [link](#)
- The Specialist Treatment of Inpatients: Caring for Diabetes in Surgery (STOIC-D Surgery) Trial: A Randomized Controlled Trial of Early Intervention With an Electronic Specialist-Led Model of Diabetes Care – [link](#) – [SPS commentary](#)
- Optimal Dose and Type of Physical Activity to Improve Glycemic Control in People Diagnosed With Type 2 Diabetes: A Systematic Review and Meta-analysis – [link](#) – [SPS commentary](#)

- A Methodological Framework for Meta-analysis and Clinical Interpretation of Subgroup Data: The Case of Major Adverse Cardiovascular Events With GLP-1 Receptor Agonists and SGLT2 Inhibitors in Type 2 Diabetes - [link](#)

### **Drug and Therapeutics Bulletin**

- Low-dose aspirin and anaemia in older people - [link](#)
- Can antidepressants worsen COPD? - [link](#)
- Effect of semaglutide on major cardiovascular events - [link](#)
- ADHD medication shortages: more than just a supply issue - [link](#)

### **European Heart Journal**

- Green cardiovascular care: a call for sustainable transformation of cardiovascular practices - [link](#)
- Seeking synergy for novel weight - and glucose-lowering pharmacotherapy and exercise training in heart failure patients with preserved ejection fraction (HFpEF) - [link](#)
- How to diagnose and treat venous congestion in heart failure - [link](#)
- The '10 commandments' for the 2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes - [link](#)
- Cannabis for chronic pain: cardiovascular safety in a nationwide Danish study – [link](#) – [SPS commentary](#)
- Aspirin-free antiplatelet strategies after percutaneous coronary interventions - [link](#)
- Cardiovascular disease risk communication and prevention: a meta-analysis - [link](#)
- Icosapent ethyl following acute coronary syndrome: the REDUCE-IT trial - [link](#)

### **European Journal of Hospital Pharmacy**

- Evaluation of the impact of pharmacist-led educational intervention on knowledge and skills of cancer patients with totally implantable venous access port: a single-centre, non-randomised controlled study - [link](#)
- Switching anti-CGRP monoclonal antibodies in chronic migraine: real-world observations of erenumab, fremanezumab and galcanezumab - [link](#)
- Enhancing pharmaceutical decision support system: evaluating antithrombotic-focused algorithms for addressing drug-related problems - [link](#)
- Physicochemical and biological stability of diluted vedolizumab in intravenous infusion bags - [link](#)
- Management of heparin-induced thrombocytopenia during extracorporeal membrane oxygenation support: a case of neutropenia caused by argatroban anticoagulation - [link](#)
- Combination of a propofol emulsion with alpha-2 adrenergic receptor agonists used for multimodal analgesia or sedation in intensive care units: a physicochemical stability study - [link](#)

### **Heart**

- Postdischarge major bleeding, myocardial infarction, and mortality risk after coronary artery bypass grafting – [link](#) – [SPS commentary](#)
- Generalisability of trials on antithrombotic treatment intensification in patients with cardiovascular disease - [link](#)
- Review of the National Institute for Health and Care Excellence guidelines on chronic heart failure - [link](#)
- Cardiogeriatrics: the current state of the art - [link](#)
- Management of pregnancy-related disorders to prevent future risk of coronary artery disease - [link](#)
- Efficacy and safety of colchicine for the treatment of myopericarditis - [link](#)

### **International Journal of Clinical Pharmacy**

- Psychiatric adverse events associated with semaglutide, liraglutide and tirzepatide: a pharmacovigilance analysis of individual case safety reports submitted to the EudraVigilance database - [link](#)
- Exploring the safety profile of tremelimumab: an analysis of the FDA adverse event reporting system - [link](#)

- Data mining and analysis of adverse event signals associated with teprotumumab using the Food and Drug Administration adverse event reporting system database - [link](#)
- A comparison between the adverse event profiles of patients receiving palbociclib and abemaciclib: analysis of two real-world databases - [link](#)
- Comparison of the sensitivities of pharmacotherapy-related and disease-specific quality of life measures in response to pharmacist-led pharmaceutical care for cancer outpatients: a randomised controlled trial - [link](#)

### **International Journal for Quality in Health Care**

- Monitoring for adverse drug events of high-risk medications with a computerized clinical decision support system: a prospective cohort study - [link](#)

### **JAMA**

- T-Cell Lymphoma From CAR T-Cell Therapy—A New Safety Notice - [link](#)
- Perioperative toripalimab plus chemotherapy for patients with resectable Non–Small Cell Lung Cancer (NSCLC): The Neotorch randomized clinical trial - [link](#)
- Intranasal naloxone for opioid overdose - [link](#)
- International Consensus Criteria for Pediatric Sepsis and Septic Shock – [link](#) – [SPS commentary](#)
- Management of Candida auris - [link](#)

### **JAMA Cardiology**

- Impact of Bempedoic Acid on Total Cardiovascular Events: A Prespecified Analysis of the CLEAR Outcomes Randomized Clinical Trial - [link](#)
- Dapagliflozin and Mode of Death in Heart Failure with Improved Ejection Fraction- A Post Hoc Analysis of the DELIVER Trial - [link](#)

### **JAMA Dermatology**

- Causes and Clinical Presentation of Drug-Induced Dermatomyositis: A Systematic Review - [link](#)
- Sustained Remission Without Corticosteroids Among Patients with Pemphigus Who Had Rituximab as First-Line Therapy - [link](#)

### **JAMA Internal Medicine**

- Early Tecovirimat Treatment for Mpox Disease Among People With HIV – [link](#) – [SPS commentary](#)
- First Trimester Use of Buprenorphine or Methadone and the Risk of Congenital Malformations - [link](#) – [SPS commentary](#)

### **JAMA Network Open**

- Cumulative update of a systematic overview evaluating interventions addressing polypharmacy - [link](#)

### **JAMA Neurology**

- Argatroban in Patients With Acute Ischemic Stroke With Early Neurological Deterioration – [link](#) – [SPS commentary](#)
- SARS-CoV-2 Vaccination and Neuroimmunological Disease: A Review - [link](#)
- Concomitant Medications for Progressive Supranuclear Palsy: A Secondary Analysis of a Randomized Clinical Trial – [link](#)

### **JAMA Oncology**

- Rapid Advances in Resectable Non–Small Cell Lung Cancer: A Narrative Review - [link](#)
- Mirtazapine as Appetite Stimulant in Patients with Non–Small Cell Lung Cancer and Anorexia: A Randomized Clinical Trial - [link](#)

### **JAMA Psychiatry**

- Prescription Stimulant Use During Pregnancy and Risk of Neurodevelopmental Disorders in Children - [link](#)

### **Journal of the American College of Cardiology**

- When Direct Oral Anticoagulants Should Not Be Standard Treatment: JACC State-of-the-Art Review - [link](#)

### **Journal of Clinical Oncology**

- Health Care Transitions Among Adolescents and Young Adults with Cancer - [link](#)
- Cancer-Associated Thrombosis: Management of a Patient with an Isolated Calf Deep Vein Thrombosis - [link](#)

### **Journal of Clinical Pharmacology**

- Inclusion of Obese Participants in Drug Development: Reflections on the Current Landscape and a Call for Action - [link](#)

### **Lancet**

- Indomethacin with or without prophylactic pancreatic stent placement to prevent pancreatitis after ERCP: a randomised non-inferiority trial – [link](#) – [SPS commentary](#)
- Lancet series on Parkinson's disease – [link](#) – [SPS commentary](#)

### **Lancet Diabetes & Endocrinology**

- Association of glycaemic index and glycaemic load with type 2 diabetes, cardiovascular disease, cancer, and all-cause mortality: a meta-analysis of mega cohorts of more than 100 000 participants - [link](#)

### **Lancet Haematology**

- Prophylaxis and management of graft-versus-host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation - [link](#)

### **Lancet HIV**

- Changes in incidence of hepatitis C virus reinfection and access to direct-acting antiviral therapies in people with HIV from six countries, 2010–19: an analysis of data from a consortium of prospective cohort studies - [link](#)
- Longitudinal trends in causes of death among adults with HIV on antiretroviral therapy in Europe and North America from 1996 to 2020: a collaboration of cohort studies - [link](#) – [SPS commentary](#)

### **Lancet Infectious Diseases**

- Oral linezolid compared with benzathine penicillin G for treatment of early syphilis in adults (Trep-AB Study) in Spain: a prospective, open-label, non-inferiority, randomised controlled trial – [link](#) – [SPS commentary](#)
- Efficacy and safety of a structured de-escalation from antipseudomonal  $\beta$ -lactams in bloodstream infections due to Enterobacterales (SIMPLIFY): an open-label, multicentre, randomised trial – [link](#) – [SPS commentary](#)
- Novel strain of multidrug non-susceptible *Neisseria gonorrhoeae* in the USA - [link](#)
- Efficacy and safety of an early oral switch in low-risk *Staphylococcus aureus* bloodstream infection (SABATO): an international, open-label, parallel-group, randomised, controlled, non-inferiority trial – [link](#) – [SPS commentary](#)

### **Lancet Oncology**

- Low-dose versus standard-dose olanzapine with triple antiemetic therapy for prevention of highly emetogenic chemotherapy-induced nausea and vomiting in patients with solid tumours: a single-centre, open-label, non-inferiority, randomised, controlled, phase 3 trial - [link](#)

### **Lancet Psychiatry**

- Efficacy and effectiveness of antipsychotics in schizophrenia: network meta-analyses combining evidence from randomised controlled trials and real-world data – [link](#) – [SPS commentary](#)

### **Lancet Public Health**

- Nitazenes—heralding a second wave for the UK drug-related death crisis? - [link](#)

### **Lancet Respiratory Medicine**

- Profiling the dysregulated immune response in sepsis: overcoming challenges to achieve the goal of precision medicine - [link](#)  
- Clarithromycin for early anti-inflammatory responses in community-acquired pneumonia in Greece (ACCESS): a randomised, double-blind, placebo-controlled trial – [link](#) – [SPS commentary](#)  
- Risk factors for COVID-19-associated pulmonary aspergillosis: a systematic review and meta-analysis – [link](#) – [SPS commentary](#)  
- Morphine for treatment of cough in idiopathic pulmonary fibrosis (PACIFY COUGH): a prospective, multicentre, randomised, double-blind, placebo-controlled, two-way crossover trial - [link](#)

### **New England Journal of Medicine**

- Navigating and Communicating about Serious Illness and End of Life - [link](#)  
- Efficacy and Safety of Acoramidis in Transthyretin Amyloid Cardiomyopathy - [link](#)  
- Oral Simnoretelvir for Adult Patients with Mild-to-Moderate Covid-19 - [link](#)  
- Testosterone Treatment and Fractures in Men with Hypogonadism - [link](#) – [SPS commentary](#)  
- Syphilis Complicating Pregnancy and Congenital Syphilis - [link](#)  
- Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma – [link](#) – [SPS commentary](#)  
- Perspective: Secondary Cancers after Chimeric Antigen Receptor T-Cell Therapy – [link](#) – [SPS commentary](#)  
- Responding to medical errors — implementing the modern ethical paradigm - [link](#)

### **Pain Physician**

- Comprehensive, Evidence-Based, Consensus Guidelines for Prescription of Opioids for Chronic Non-Cancer Pain from the American Society of Interventional Pain Physicians - [link](#)

### **Pediatrics (American Academy of Pediatrics)**

- 2023 American Heart Association and American Academy of Pediatrics Focused Update on Neonatal Resuscitation: An Update to the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care - [link](#)

### **Pharmaceutical Journal**

- Inclisiran: the 'extremely unusual' political influence behind the novel drug's approval - [link](#)

### **Prescribe International – February 2024** includes

- Olaparib (Lynparza<sup>®</sup>) as "maintenance" therapy for certain advanced ovarian cancers after first-line chemotherapy; Clomifene: serious, sometimes irreversible, vision disorders; Drugs that interfere with the placenta and affect the fetus – with editorial

### **Rheumatic & Musculoskeletal Diseases**

- Hormonal and reproductive factors in relation to the risk of rheumatoid arthritis in women: a prospective cohort study with 223 526 participants – [link](#) – [SPS commentary](#)

### **Thorax**

- Genetic and T2 biomarkers linked to the efficacy of HDM sublingual immunotherapy in asthma – [link](#) – [SPS commentary](#)  
- Use of inhaled corticosteroids and the risk of hospitalisation for pneumonia in children with asthma: a nationwide cohort study - [link](#)

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## **CONSULTATIONS (new additions in bold)**

### **Australian Commission on Safety and Quality in Health Care (ACSQHC)**

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Advancing quality use of medicines in NSW public hospitals and the wider community since 1988  
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An initiative of NSW clinical pharmacologists & pharmacists  
ABN: 82 707 308 091

- NPAAC Standards - Tier 3B and 4, Closing 23 February 2024 - [link](#)
- Updating the National Guidelines for On-Screen Presentation of Discharge Summaries, Closing 20 February 2024 - [link](#)

#### TGA

- Proposed amendments to the Poisons Standard – ACMS, ACCS and Joint ACMS-ACCS meetings, March 2024, Closes on 5 February 2024 - [link](#)

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#### WEBINARS & PODCASTS

##### Australian Prescriber Podcasts

- [Episode 156](#) – Physical health monitoring for people with schizophrenia

##### MJA Podcasts

- [Episode 1](#): chronic cough in children and adults
- [Episode 2](#): the economics of Australia's health system

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#### UPCOMING EVENTS

(New additions listed in TAGMail - click [here](#) for the running list of other events)

##### Kids Research, Sydney Children's Hospitals Network

- How to get 'grant ready' – free workshop, Friday, 9 February, 9:30am-12:30pm, Teams and Royal Hospital for Women Lecture Theatre – register [here](#)

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## Fortnightly TAG Mail – resources list

## 18<sup>th</sup> January 2024



**NSW TAG wishes all TAGMail readers  
a happy, healthy and productive 2024**

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#### NSW TAG ACTIVITIES

##### Upcoming TAG meetings

Meeting for NSW TAG's feedback re Dept of Health's proposed Repurposing Medicines Program 12-1pm Thursday 25<sup>th</sup> January. Contact Sasha Bennett [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) if wish to provide input.

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#### OTHER NEWS (new additions in bold)

##### NSW Health

- Measles alert for western Sydney - [link](#)
- Legionnaires' disease alert for Sydney CBD - [link](#)
- NSW community urged to stay COVID-safe this summer - [link](#)

##### Pharmacy Board of Australia

- New accreditation standards for pharmacist prescriber education programs – [link](#)

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- Pharmacist prescribing position statement update - [link](#)

#### TGA

- [Repeal](#) of Therapeutic Goods (Restricted and Prohibited Representations—Nicotine) Permission (No. 2) 2021 – advertising permission for nicotine repealed as part of the vaping regulation reforms

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### REPORTS AND PUBLICATIONS – AUSTRALIA

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#### Agency for Clinical Innovation, NSW (ACI)

- The latest weekly Evidence Digests can be found [here](#)
- Diagnosis and management of adults with acute ureteric colic - [link](#) – [patient fact sheet](#)

#### Australian Commission on Safety and Quality in Health Care (ACSQHC)

- National Safety and Quality Cosmetic Surgery Standards - [link](#)
- National Consensus Statement: Essential elements for safe and high-quality end-of-life care - [link](#)

#### Australian Government Department of Health

- Launch of the National Immunisation Program Vaccinations in Pharmacy (NIPVIP) Program - [link](#)
- Hospital data resources - [link](#)

#### Australian Institute for Health and Welfare (AIHW)

- Australian facts: [Heart, stroke and vascular disease](#), [Diabetes](#), [Chronic kidney disease](#)

#### CEC

- Fall Prevention in NSW. White Paper 2023 - [link](#)

#### MIMS monthly updates – [January 2024](#)

- New Products
  - [Raxtozinameran](#) (Comirnaty Omicron XBB.1.5). Indicated for active immunisation to prevent COVID-19 in those 5 years of age and older as per official recommendations.
- New Indications
  - Incobotulinumtoxin A ([Xeomin](#)) for adult chronic sialorrhoea due to neurological disorders; and in children and adolescents aged 2 to 17 years for the symptomatic treatment of chronic sialorrhoea due to neurological/neurodevelopmental disorders and for spasticity of the lower and/or upper limbs
  - Olaparib ([Lynparza](#)) expanded indications in breast cancer and prostate cancer.

#### TGA

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
  - Andexxa ([andexanet alfa](#)) is provisionally approved for adult patients treated with a direct factor Xa inhibitor when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding
  - Imjudo ([tremelimumab](#)) for the treatment of unresectable hepatocellular carcinoma
  - Imfinzi ([durvalumab](#)) for the treatment of unresectable hepatocellular carcinoma
  - [Opdualag](#) (nivolumab and relatlimab), which is approved for the treatment of patients with unresectable or metastatic melanoma who are at least 12 years old
- Australian prescription medicine decision summaries:
  - Raniviz ([ranibizumab](#)) is approved to treat visual impairment issues
  - Aquipta ([atogepant](#)) is approved for prophylaxis of migraine in adults
  - Givlaari ([givosiran](#)) is approved to treat acute hepatic porphyria
  - Sohonos ([palovarotene](#)) is approved to reduce the formation of heterotopic ossification
  - Beyfortus ([nirsevimab](#)) is approved for the prevention of respiratory syncytial virus (RSV) in neonates, infants and vulnerable children up to the age of 24 months
  - Spevigo ([spesolimab](#)) is approved for the treatment of flares in adult patients with generalised pustular psoriasis

-- Heparin Interpharma ([heparin sodium](#)) is approved for prophylaxis and treatment of deep vein thrombosis in patients 18 years and older

### Victorian Institute of Forensic Medicine

- Clinical Communiqué Volume 10 Issue 4 December 2023 - [link](#)

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## REPORTS AND PUBLICATIONS – INTERNATIONAL

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### Canadian Agency for Drugs and Technologies in Health

- Leucovorin Dosing for Gastrointestinal Cancer – [link](#)
- Ketamine for Chronic Non-Cancer Pain: A 2023 Update - [link](#)
- Horizon scan: Emerging Drugs for Relapsed or Refractory Peripheral T-Cell Lymphoma - [link](#)
- Reference list: Screening for Thyroid Dysfunction Using Thyroid Stimulating Hormone Testing - [link](#)

### electronic Medicines Compendium (eMC) (UK)

- [New products](#)
- Colextra-D3 (Colecalciferol) 20,000 IU Soft Capsules for prevention and treatment of vitamin D deficiency in adults and adolescents with an identified risk. It may be used as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency
- Kalydeco (ivacaftor) granules in sachet - monotherapy for cystic fibrosis (CF) in children ≥1 month, weighing 3-25kg with specific CFTR mutations. Also licensed as part of ivacaftor/tezacaftor/elexacaftor regimen for CF in children aged 2-5yrs who have ≥1 F508del mutation
- Hydrocortisone 10mg/5ml and 5mg/5ml oral solutions licensed for replacement therapy in adrenal insufficiency in infants, children and adolescents (from 1 month to <18 years old)
- Veozza ([fezolinetant](#)) tablets - non-hormonal selective neurokinin 3 receptor antagonist licensed for the treatment of moderate to severe vasomotor symptoms associated with menopause
- New indications/expanded access
- Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide fumarate) - extension for use in paediatric patients from age 2 years, weighing at least 14kg for the treatment of HIV 1, without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir
- Evrysdi (risdiplam) for all age groups (previously for use from age 2 months and older). It now includes data from the RAINBOWFISH trial in 18 patients with pre-symptomatic spinal muscular atrophy between 16 and 40 days of age
- Nuvaxovid dispersion for injection, COVID-19 Vaccine (recombinant, adjuvanted) - extension as a booster dose in the adolescent population from 12 to 18 years, including as a heterologous booster
- Zerbaxa (tazobactam and ceftolozane) - extension for Zerbaxa for complicated intra-abdominal infection, acute pyelonephritis and complicated urinary tract infections in paediatric patients

### European Medicines Agency (EMA)

- Human medicines: highlights of [2023](#) – and of [2024](#)
- CHMP approved new indications
- [HyQvia](#) (human normal immunoglobulin) for use in adults, children and adolescents with chronic inflammatory demyelinating polyneuropathy, as maintenance immunomodulatory therapy after stabilization with IVIg
- Tenecteplase ([Metalyse](#)) for thrombolytic treatment of acute ischaemic stroke in adults, within 4.5 hours from last known well and after exclusion of intracranial haemorrhage – also new formulation/strength of 5000 units (25 mg) powder for solution for injection
- CHMP approved extensions of use
- bezlotoxumab ([Zinplava](#)) for prevention/recurrence of CDI in all patients aged 1 year and older
- [VeraSeal](#) (human fibrinogen/human thrombin) for improvement of haemostasis and as suture support in vascular surgery for all age groups
- CHMP marketing authorisation
- [Dabigatran Etxilate Leon Farma](#) generic to Pradaxa – [SPS commentary](#)
- eribulin ([Mevlyq](#)) generic to Halaven for the treatment of breast cancer and liposarcoma
- [etrasimod](#) (Velsipity) for treatment of ulcerative colitis

- [Ibuprofen Gen.Orph](#) generic to Pedea for the treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants
- [omaveloxolone](#) (Skyclarys) for the treatment of Friedreich's ataxia
- [Pomalidomide Viatrix](#) generic to Imnovid for the treatment of multiple myeloma

### Food and Drug Administration (FDA) USA

- New Drug approvals
- Two gene therapies (Casgevy and Lyfgenia) to treat sickle cell disease - [link](#)
- [pembrolizumab](#) with chemoradiotherapy for FIGO 2014 Stage III-IVA cervical cancer
- [Filsuvez](#) (birch triterpenes) to treat wounds associated with dystrophic and junctional epidermolysis bullosa
- [Wainua](#) (eplontersen) to treat polyneuropathy of hereditary transthyretin-mediated amyloidosis
- Berdazimer topical ([Zelsuvmi](#)) - topical nitric oxide-releasing agent for molluscum contagiosum in patients aged 1 year and older
- Roflumilast topical ([Zoryve](#)) - new foam dosage form and new indication approved for seborrheic dermatitis in patients aged 9 years and older
- Immune globulin IV ([Bivigam](#)) - indication for primary immunodeficiency expanded to include children aged 2 years and older
- Enfortumab Vedotin Plus Pembro for Urothelial Cancer - [link](#)
- Tralokinumab for Treating Eczema in Adolescents - [link](#)
- Antiparasitic for High-Risk Neuroblastoma - [link](#)
- Iptacopan to Treat Paroxysmal Nocturnal Hemoglobinuria - [link](#)
- Idacio ([Adalimumab-Aacf](#)), tumor necrosis factor (TNF) blocker

### Health Canada

- Handbook for healthcare professionals on biosimilar biologic drugs - [link](#)

### Health Services Safety Investigation Body

- Electronic patient record systems: recurring themes arising from safety investigations - [link](#)

### Medicines and Healthcare products Regulatory Agency (MHRA)

- Opdualag licensed for patients with advanced melanoma - [link](#)

### NHS Scotland - Scottish Medicines Consortium

- Accepted for use:
- [Bimekizumab](#) (Bimzelx®) for axial spondyloarthritis
- [Cemiplimab](#) (Libtayo®) for cutaneous squamous cell carcinoma
- [Cipaglucosidase alfa](#) (Pombiliti®) for Pompe disease – [SPS commentary](#)
- [Degarelix](#) (Firmagon®) for prostate cancer
- [Deucravacitinib](#) (Sotyktu®) for plaque psoriasis
- [Nivolumab](#) (Opdivo®) for non-small cell lung cancer
- [Trastuzumab](#) deruxtecan (Enhertu®) for unresectable or metastatic HER2-low breast cancer

### National Institute for Health and Care Excellence (NICE) UK

- Pembrolizumab plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer ([TA939](#))
- Risdiplam for treating spinal muscular atrophy, updated ([TA755](#))
- Empagliflozin for treating chronic kidney disease ([TA942](#)) – [SPS commentary](#)
- Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes ([TA943](#))
- Targeted-release budesonide for treating primary IgA nephropathy ([TA937](#))
- Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer ([TA944](#))
- Velmanase alfa for treating alpha-mannosidosis - Highly specialised technologies guidance ([HST29](#))
- Sebelipase alfa for treating Wolman disease ([HST30](#))

- Cardiovascular disease: risk assessment & reduction, including lipid modification, updated ([NG238](#)) – [SPS commentary](#)
- Acne vulgaris: management ([NG198](#))
- NICE publishes additional resources to support implementation of guidance on digitally enabled therapies for adults with anxiety disorders ([HTE9](#)) or depression ([HTE8](#)) – [SPS commentary](#)
- Epilepsies in children, young people and adults ([QS211](#))
- Transition from children's to adults' services ([QS140](#))
- Bipolar disorder: assessment and management, updated ([CG185](#))

### National Institute for Health and Care Research (NIHR)

- NIHR alert: Women need support to improve their health before pregnancy - [link](#)
- NIHR Alert: Tool could reduce blood test monitoring for most people on methotrexate - [link](#)
- The potential impact of policies and structural interventions in reducing cardiovascular disease and mortality: a systematic review of simulation based studies - [link](#)

### Neonatal & Paediatric Pharmacists Group

- Guideline for peripheral use of adrenaline and noradrenaline in paediatric patients without central access - [link](#)

### Scottish Intercollegiate Guideline Network (SIGN) UK

- Perinatal mental health conditions: [SIGN 169](#)

### Specialist Pharmacy Services NHS UK

- Supporting adherence: [Complex medication regimens](#) ([SPS commentary](#)), [Defining and understanding medication adherence](#) ([SPS commentary](#)), [Explaining how to use or take medicines](#) ([SPS commentary](#)), [Manual dexterity](#) ([SPS commentary](#)), [Reminding to take medicines](#) ([SPS commentary](#)), [Swallowing difficulties](#) ([SPS commentary](#))
- Natalizumab biosimilar: patient information sheet - [link](#)
- Use of nefopam for chronic pain - [link](#)
- SPS spotlight monthly digest – [December 2023](#)

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## MEDICATION SAFETY

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### All Wales Therapeutics and Toxicology Centre

- Withdrawal of national desflurane contract in Wales - [link](#)

### British National Formulary

- BNF/BNFC Newsletter: [December 2023](#)
- includes: MHRA advice on reports of myasthenia gravis with statins, updated guidance for prevention of secondary cases of diphtheria, and updated safety information to highlight difference between benzylpenicillin sodium and benzathine benzylpenicillin

### electronic Medicines Compendium (eMC) (UK)

- [Revised SPCs](#)
- Avelox (moxifloxacin) - possible risk of prolonged, disabling & potentially irreversible serious ADRs highlighted – [SPS commentary](#)
- Azacitidine Seacross - cutaneous vasculitis added as undesirable ADR (unknown frequency)
- Beovu (brovacizumab) dosing for wet age-related macular degeneration and the treatment timelines for the diabetic macular oedema indication updated
- Brintellix (vortioxetine hydrobromide) - dyspepsia, akathisia, bruxism, trismus, restless leg syndrome, tremor, discontinuation syndrome, vision blurred, and galactorrhoea included as ADRs
- Brukinsa (zanubrutinib) - updated information on interactions between zanubrutinib and moderate (fluconazole and diltiazem) and strong (voriconazole and clarithromycin) CYP3A inhibitors, which resulted in increased zanubrutinib exposures

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- Ciproxin (ciprofloxacin) - possible risk of prolonged, disabling and potentially irreversible serious ADRs highlighted – [SPS commentary](#)
- EpiPen Adrenaline (epinephrine) - additional side effects under cardiac, respiratory & administration site disorders and to state “adrenaline excreted in breast milk would not have effect on nursing infant”
- Erythromycin ethyl succinate - contraindication with lomitapide due to markedly increased transaminase levels with concomitant use, a warning to use with caution with corticosteroids and information on risk of congenital malformations after use during pregnancy – [SPS commentary](#)
- Enbrel (etanercept) - glomerulonephritis is now listed as a potential ADR (frequency unknown)
- Femoston-conti estradiol hemihydrate/dydrogesterone) - contraceptives containing oestrogens shown to significantly decrease plasma concentrations of lamotrigine, potentially lowering seizure control, and although interaction between HRT & lamotrigine not been studied, it is expected that similar interaction exists
- Furosemide - lichenoid reactions as a rare ADR
- Kalydeco - concomitant use of CYP3A inhibitors updated to advise dose reduction is based on dose recommended for the age and weight and to refer to Table 2 for the recommended dose
- Mayzent (siponimod fumaric acid) information added on squamous cell carcinoma, herpes viral infection, cryptococcal meningitis and monitoring of treatment effect on lymphocytes
- Moxifloxacin - risk of disabling and potentially long-lasting or irreversible ADRs, sometimes affecting multiple systems, with fluoroquinolone antibiotics – use only when other antibiotics are inappropriate – [SPS commentary](#)
- Nivestim (filgrastim) - in post-marketing setting, myelodysplastic syndrome and acute myeloid leukaemia have been associated with the use of pegfilgrastim, an alternative G-CSF medicine, in conjunction with chemotherapy and/or radiotherapy in breast and lung cancer patients
- Octasa (mesalazine) - eosinophilia and systemic symptoms (DRESS) as an ADR and to note mesalazine may produce red-brown discolouration after contact with sodium hypochlorite bleach
- Protium (pantoprazole) - severe cutaneous ADRs, reports of false-positive results in some urine screening tests for tetrahydrocannabinol, and updated information on undesirable effects
- Rozlytrek (entrectinib) - use in patients with congestive heart failure (CHF) updated to note CHF reported in less than 5% of patients with/without a history of cardiac disease in clinical trials with entrectinib. Reactions resolved in 70% of those patients after appropriate management
- Suboxone Tablets (naloxone/buprenorphine) - recommended starting dose in adults and adolescents >15 years is 4 mg/1 mg and can be repeated up to a maximum dose of 12 mg/ 3 mg on day 1 to minimise undue withdrawal symptoms and retain the patient in treatment
- Targinact (oxycodone/naloxone) – more added on treatment goals and discontinuation. Central sleep apnoea syndrome (unknown frequency) and drug dependence (rare) added as ADRs, and toxic leukoencephalopathy after an oxycodone overdose – [SPS commentary](#)
- Tecfidera (dimethyl fumarate) - Tecfidera pregnancy registry study results included, in which 289 prospectively collected pregnancy outcomes were documented in patients with MS who were exposed to dimethyl fumarate
- Tezspire (tezepelumab) - anaphylactic reaction a possible ADR (unknown frequency)
- Tixylix Cough Syrup - pharmacodynamic properties now mentions that glycerol has demulcent properties and may possibly block sensory cough receptors in the respiratory tract
- Zamadol (tramadol hydrochloride) risk of dependence and addiction with opioids - [SPS commentary](#)
- Risk minimisation materials
- Casgevy (exagamglogene autotemcel): Patient Alert Card - for patients to carry with them at all times, & notifies healthcare professionals the patient has received this treatment. Patients are at increased risk of bleeding due to possibility of a prolonged period of thrombocytopenia prior to platelet engraftment
- [Tresiba](#)® (insulin degludec) - safety information for healthcare professionals regarding two product strengths, 100units/mL & 200units/mL, and potential risk of dosing error. Both pens have dose display set in the dial in UNITS so no dose conversion is required if transferring patients between strengths – [SPS commentary](#) – and [poster](#) – [SPS commentary](#)

## EMA

- First version of the European Union (EU) list of critical medicines agreed to help avoid potential shortages in the EU – [link](#) – [SPS commentary](#)
- PRAC meeting [highlights](#): New safety information for healthcare professionals: new precautionary measures for valproate-containing medicines; Start of safety review of CAR T-cell medicines
- Potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines: PRAC recommends precautionary measures - [link](#)

### **Food and Drug Administration (FDA) USA**

- Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicines approved for type 2 diabetes and obesity - [link](#)
- Updates to labelling for promethazine hydrochloride injection products - [link](#)
- Updates to labelling for Two Cholesterol-Lowering Agents - [link](#)

### **Institute for Safe Medication Practices (ISMP) USA**

- Medication Safety Alert! [January 11, 2024](#)
- High-Alert Medication List for acute care settings updated for 2024 - [link](#)
- Medication Safety Alert! [December 14, 2023](#)
- ISMP 26th Annual Cheers Awards: Hitting the Safety High Notes - [link](#)

### **MedEffect, Canada**

- Health Product InfoWatch, [December 2023](#)

### **Medicines and Healthcare products Regulatory Agency (MHRA) UK**

- MHRA update on new study on risk in children born to men taking valproate - [link](#)
- Drug Safety Update [December 2023](#)
- Aripiprazole (Abilify and generic brands): risk of pathological gambling - [link](#)
- Vitamin B12 (hydroxocobalamin, cyanocobalamin): advise patients with known cobalt allergy to be vigilant for sensitivity reactions – [link](#) – [SPS commentary](#)

### **Medsafe (New Zealand Medicines and Medical Devices Safety Authority)**

- Prescriber Update – [December 2023](#) includes
- Spotlight on dulaglutide - [link](#)
- Discuss possible effects on uterine bleeding in people taking oral anticoagulant therapy - [link](#)
- DPP-4 inhibitors and the possible risk of ileus - [link](#)
- Sodium valproate (Epilim) use in people who can father children: important new safety [information](#)

### **MIMS monthly updates – January 2024**

- New Contraindications
- Romosozumab ([Evenity](#)) in patients with a history of myocardial infarction or stroke
- Trimethoprim and sulfamethoxazole ([Septrin](#) Sugar Free Oral Liquid) in patients with documented megaloblastic anaemia due to folate deficiency, evidence of marked parenchymal damage or blood dyscrasia; in pregnancy (any stage) and in nursing mothers

### **Specialist Pharmacy Services NHS UK**

- Using vitamin D during breastfeeding - [link](#)
- Managing interactions with methotrexate - [link](#)
- Using metronidazole during breastfeeding - [link](#)
- Medication safety update: [December 2023](#)
- Managing interactions with direct oral anticoagulants (DOACs) - [link](#) – [SPS commentary](#)
- Understanding direct oral anticoagulant (DOAC) interactions - [link](#) – [SPS commentary](#)

### **TGA**

- Shortages: [Vyvanse](#) (lisdexamfetamine dimesilate) capsules and [update](#), [Bicillin L-A](#) (benzathine benzylpenicillin tetrahydrate) prefilled syringe for injection, Substitution approved for [fluoxetine 20 mg dispersible](#) tablets (Zactin Tabs)

- Product Information safety updates - [December 2023](#)
- Romosozumab (Evenity) - new warnings about the risk of heart attack and stroke - [link](#)
- Compounding safety information: semaglutide-like products - [link](#)
- Products containing undeclared sildenafil: [BAIWEI Maximum Powerful](#) tablets, [Bigger Longer More Time More Sperms](#) capsules, [Ying Da Wang](#) tablets - blood pressure may be lowered to dangerous levels
- Product containing undeclared sibutramine: [Li Da Daidaihua](#) capsules - increased risk of cardiac events and stroke
- Safety alert and product recalls: updated advice following *Ralstonia pickettii* contamination of some saline products - [link](#)

### UK Health Security Agency

- Vaccine update: issue 344, November 2023, pregnancy special - [link](#)

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## PAPERS OF INTEREST

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### Annals of Emergency Medicine

- Tranexamic acid for traumatic injury in the emergency setting: A systematic review and bias-adjusted meta-analysis of randomized controlled trials - [link](#)

### Annals of Internal Medicine

- Cumulative Incidence of Thiazide-Induced Hyponatremia: A Population-Based Cohort Study - [link](#) – [SPS commentary](#)

### Arthritis & Rheumatology

- Poly-refractory Rheumatoid Arthritis: An Uncommon Subset of Difficult to Treat Disease with Distinct Inflammatory and Non-inflammatory Phenotypes - [link](#)
- The incidence of uveitis in patients with axial spondylarthritis treated with biologics or targeted synthetics: a systematic review and network meta-analysis - [link](#)

### Australian Prescriber

- Physical health monitoring for people with schizophrenia - [link](#)
- Editorial: National Medicines Policy 2.0—what's changed and what's next? - [link](#)
- Gabapentinoids: a therapeutic review - [link](#)
- Ongoing challenges of off-label prescribing - [link](#)
- Top 10 drugs [2021–22](#); Top 10 drugs [2022–23](#)
- Herpes zoster (shingles) vaccination update - [link](#)
- New drugs: [Pneumococcal 15-valent and 20-valent conjugate vaccines](#) for prevention of pneumococcal disease; [Tirzepatide](#) for type 2 diabetes; [Vericiguat](#) for chronic heart failure

### BMC Med

- Development of prescribing indicators related to opioid-related harm in patients with chronic pain in primary care- a modified e-Delphi study - [link](#)

### British Journal of Clinical Pharmacology

- Pharmacokinetics of ceftazidime-avibactam in a critically ill patient under high-volume continuous venovenous haemodiafiltration: A first paediatric case report - [link](#)
- Plasma 6β-hydroxycortisol to cortisol ratio as a less invasive cytochrome P450 3A phenotyping method - [link](#)
- The correlation between 4 adherence measurements methods in patients with rheumatoid arthritis using methotrexate - [link](#)
- Enteral Administration of Crushed Rilpivirine in a Patient with HIV: A Case Report - [link](#)
- Effect of changes in metabolic enzymes and transporters on drug metabolism in the context of liver disease: impact on pharmacokinetics and drug-drug interactions - [link](#)

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### **British Journal of Psychiatry**

- Features of immunometabolic depression as predictors of antidepressant treatment outcomes: pooled analysis of four clinical trials - [link](#)

### **British Medical Journal (BMJ)**

- Europe suspends hundreds of generic drugs over serious data concerns - [link](#)  
- Advances in the management of pancreatic cancer - [link](#)  
- Management of chronic pain secondary to temporomandibular disorders: a systematic review and network meta-analysis of randomised trials – [link](#) – [SPS commentary](#)

### **BMJ Open**

- Clinical impacts of an integrated electronic health record-based smoking cessation intervention during hospitalisation - [link](#)  
- Adverse drug events associated with nortriptyline compared with paroxetine and alternative medications in an older adult population: a retrospective cohort study in Southern California - [link](#)

### **BMJ Quality & Safety**

- Initial opioid prescription characteristics and risk of opioid misuse, poisoning and dependence: retrospective cohort study - [link](#)

### **Circulation**

- Dapagliflozin and Apparent Treatment-Resistant Hypertension in Heart Failure with Mildly Reduced or Preserved Ejection Fraction: The DELIVER Trial - [link](#)  
- Current Status and Principles for the Treatment and Prevention of Diabetic Foot Ulcers in the Cardiovascular Patient Population: A Scientific Statement From the American Heart Association - [link](#)  
- Flecainide is associated with a lower incidence of arrhythmic events in a large cohort of patients with catecholaminergic polymorphic ventricular tachycardia - [link](#)

### **Circ Heart Fail**

- Effect of Dapagliflozin Versus Placebo on Symptoms and 6-Minute Walk Distance in Patients with Heart Failure: The DETERMINE Randomized Clinical Trials - [link](#)

### **Cochrane**

- Pharmacological interventions for the prevention of bleeding in people undergoing elective hip or knee surgery: a systematic review and network meta-analysis - [link](#)  
- Anticoagulation for people receiving long-term haemodialysis - [link](#)  
- Vitamin B12 supplementation during pregnancy for maternal and child health outcomes - [link](#)  
- Ibuprofen for acute postoperative pain in children - [link](#)  
- Population-based interventions for preventing falls and fall-related injuries in older people - [link](#)  
- Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis - [link](#)  
- Maintenance therapy for chronic lymphocytic leukaemia - [link](#)  
- Pharmacological interventions for pruritus in adult palliative care patients - [link](#)  
- Diclofenac for acute postoperative pain in children - [link](#)  
- Lamotrigine add-on therapy for drug-resistant focal epilepsy - [link](#)  
- Anticholinergic deprescribing interventions for reducing risk of cognitive decline or dementia in older adults with and without prior cognitive impairment - [link](#)  
- Corticosteroids for preventing postherpetic neuralgia - [link](#)

### **Diabetes Care**

- Diabetes Care Standards of Care in Diabetes 2024 – [link](#) – [SPS commentary](#)  
- Fetal Overgrowth and Preterm Delivery in Women With Type 1 Diabetes Using Insulin Pumps or Multiple Daily Injections: A Post Hoc Analysis of the EVOLVE Study Cohort - [link](#)  
- Outcomes With Finerenone in Patients With Chronic Kidney Disease and Type 2 Diabetes by Baseline Insulin Resistance - [link](#)



### **Diabetes, Obesity and Metabolism**

- Glucagon-like peptide-1 receptor agonists and risk of thyroid cancer: A systematic review and meta-analysis of randomised controlled trials - [link](#)
- Efficacy and safety of semaglutide 2.4 mg for weight loss in overweight or obese adults without diabetes: An updated systematic review and meta-analysis including the 2-year STEP 5 trial - [link](#)
- Effect of sodium-glucose cotransporter-2 inhibitors on myocardial infarction incidence: A systematic review and meta-analysis of randomized controlled trials and cohort studies - [link](#)

### **European Heart Journal**

- Oral anticoagulation after atrial fibrillation catheter ablation: benefits and risks - [link](#)
- Oral strategies to target proprotein convertase subtilisin/kexin type 9 and lipoprotein(a): the new frontier of lipid lowering - [link](#)

### **European Journal of Hospital Pharmacy**

- Physicochemical and biological stability of diluted vedolizumab in intravenous infusion bags - [link](#)
- Therapeutic drug monitoring of vancomycin in the case of augmented renal clearance: a case report of a paediatric patient - [link](#)
- No effects of nirmatrelvir/ritonavir on darunavir plasma trough concentrations: a case report - [link](#)
- Switching anti-CGRP monoclonal antibodies in chronic migraine: real-world observations of erenumab, fremanezumab and galcanezumab - [link](#)
- Inhaled aztreonam lysine in the management of Pseudomonas aeruginosa in patients with cystic fibrosis: real-life effectiveness - [link](#)
- Evaluation of the stability of aciclovir in elastomeric infusion devices used for outpatient parenteral antimicrobial therapy - [link](#)

### **Heart**

- Cardiovascular sequelae of trastuzumab and anthracycline in long-term survivors of breast cancer – [link](#) – [SPS commentary](#)
- Diagnosis and management of resistant hypertension - [link](#)

### **Internal Medicine Journal**

- Transitioning patients from intravenous to subcutaneous infliximab and vedolizumab for inflammatory bowel disease: what is the opportunity cost of improving access to healthcare? - [link](#)

### **International Journal of Clinical Pharmacy**

- The prevalence of hepatic and thyroid toxicity associated with imatinib treatment of chronic myeloid leukaemia: a systematic review - [link](#)
- Assessing safety concerns of interstitial lung disease associated with antibody-drug conjugates: a real-world pharmacovigilance evaluation of the FDA adverse event reporting system - [link](#)
- Valproic acid for agitation in the intensive care unit: an observational study of psychiatric consults - [link](#)

### **JAMA**

- Metformin Plus Insulin for Preexisting Diabetes or Gestational Diabetes in Early Pregnancy: The MOMPOD Randomized Clinical Trial – [link](#) – [SPS commentary](#)
- Dementia in Women Using Estrogen-Only Therapy - [link](#)

### **JAMA Cardiology**

- Dual Antiplatelet Therapy De-Escalation in Stabilized Myocardial Infarction With High Ischemic Risk: Post Hoc Analysis of the TALOS-AMI Randomized Clinical Trial - [link](#)
- Optimization of Evidence-Based Heart Failure Medications After an Acute Heart Failure Admission: A Secondary Analysis of the STRONG-HF Randomized Clinical Trial – [link](#) – [SPS commentary](#)

### **JAMA Dermatology**

- Risk of Paradoxical Eczema in Patients Receiving Biologics for Psoriasis - [link](#)

### **JAMA Internal Medicine**

- Safety of GLP-1 Receptor Agonists and Other Second-Line Antidiabetics in Early Pregnancy - [link](#)

### **JAMA Network Open**

- Mortality and Morbidity Among Individuals with Hypertension Receiving a Diuretic, ACE Inhibitor, or Calcium Channel Blocker - [link](#)

### **JAMA Neurology**

- Brexpiprazole for the Treatment of Agitation in Alzheimer Dementia: A Randomized Clinical Trial – [link](#) – [SPS commentary](#)

### **JAMA Oncology**

- Research letter: GLP-1 Receptor Agonists and Colorectal Cancer Risk in Drug-Naive Patients With Type 2 Diabetes, With and Without Overweight/Obesity - [link](#)

### **JAMA Psychiatry**

- Pharmacologic Treatment of Schizophrenia Beyond Dopamine Receptor Blockade—Has Its Time Come Yet? - [link](#)

- Benzodiazepine Use During Pregnancy and Risk of Miscarriage - [link](#)

### **Journal of the American College of Cardiology**

- Safety and Tolerability of Inclisiran for Treatment of Hypercholesterolemia in 7 Clinical Trials - [link](#)

### **Journal of Pharmacy Practice and Research (JPPR)**

- Editorial: The challenge of drug prescribing for older people - [link](#)

- Multidisciplinary care of older adults in the emergency department to influence deprescribing in older adults: a cohort study - [link](#)

- Vitamin B12 deficiency in older people: a practical approach to recognition and management - [link](#)

### **Lancet Haematology**

- Indication and management of allogeneic haematopoietic stem-cell transplantation in myelofibrosis: updated recommendations by the EBMT/ELN International Working Group - [link](#)

### **Lancet Infectious Diseases**

- Guidelines for the management of Toxoplasma gondii infection and disease in patients with haematological malignancies and after haematopoietic stem-cell transplantation: guidelines from the 9th European Conference on Infections in Leukaemia, 2022 - [link](#)

### **Lancet Neurology**

- Corticosteroids versus clobazam for treatment of children with epileptic encephalopathy with spike-wave activation in sleep (RESCUE ESES): a multicentre randomised controlled trial - [link](#)

- Blood–brain barrier dysfunction in multiple sclerosis: causes, consequences, and potential effects of therapies - [link](#)

- Neurological adverse events of immune checkpoint inhibitors and the development of paraneoplastic neurological syndromes - [link](#)

### **Lancet Psychiatry**

- Psychopharmacology in children and adolescents: unmet needs and opportunities - [link](#)

- Clozapine: past, present, and future - [link](#)

### **Lancet Oncology**

- Effect of baseline oestradiol serum concentration on the efficacy of anastrozole for preventing breast cancer in postmenopausal women at high risk: a case-control study of the IBIS-II prevention trial - [link](#)

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### **Medical Journal of Australia**

- Chronic suppurative lung disease and bronchiectasis in children, adolescents and adults in Australia and New Zealand: TSANZ position statement summary - [link](#)
- Considerations of delayed gastric emptying with peri-operative use of glucagon-like peptide-1 receptor agonists - [link](#)
- Cough in Children and Adults: Diagnosis, Assessment and Management (CICADA). Summary of an updated position statement on chronic cough in Australia - [link](#)

### **New England Journal of Medicine**

- Mirvetuximab Soravtansine in FR $\alpha$ -Positive, Platinum-Resistant Ovarian Cancer - [link](#)
- Chronic Lymphocytic Leukemia Therapy Guided by Measurable Residual Disease - [link](#) – [SPS commentary](#)
- Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone (D-VRd) for Multiple Myeloma - [link](#)
- Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults – [link](#) – [SPS commentary](#)
- Cannabis-Related Disorders and Toxic Effects - [link](#)

### **Pediatrics**

- Vaccine Effectiveness Against Long COVID in Children - [link](#)
- Case report: Neonatal Opioid Withdrawal Syndrome Following Prenatal Use of Supplements Containing Tianeptine - [link](#)
- Advances in the Care of Infants With Prenatal Opioid Exposure and Neonatal Opioid Withdrawal Syndrome - [link](#)

### **Pharmaceutical Journal**

- Coroner advises NHS England to take action to raise awareness about interaction between tramadol and warfarin following death of a patient - [link](#)
- Pharmaceutical journal develops new series of articles mapped to Royal Pharmaceutical Society's 'competency framework for all prescribers' - [link](#)

### **Pharmacotherapy**

- Multicenter study evaluating target attainment of anti-Factor Xa levels using various enoxaparin prophylactic dosing practices in adult trauma patients - [link](#)
- Real world study on elexacaftor-tezacaftor-ivacaftor impact on cholesterol levels in adults with cystic fibrosis - [link](#)
- Is reversal of anticoagulants necessary in neurologically intact traumatic intracranial hemorrhage? - [link](#)
- Identification of risk factors associated with acute kidney injury in patients taking sodium-glucose cotransporter-2 inhibitors - [link](#)
- Clinical outcomes associated with anti-Xa-monitored enoxaparin for venous thromboembolism prophylaxis - [link](#)

### **Prescribe International – [January 2024](#) includes**

- Editorial "[Safety signals: why bother?](#)"; Abemaciclib (Verzenio<sup>®</sup>), palbociclib (Ibrance<sup>®</sup>) & ribociclib (Kisqali<sup>®</sup>) added to an aromatase inhibitor in certain breast cancers; When the cause of a disorder is not immediately obvious: could a drug be responsible?; Prescribing cascades: recognise them and take corrective action; Defending the right to compensation for the victims of drug-induced harms

### **Stroke**

- Management of Poststroke Hyperglycemia: Results of the TEXAIS Randomized Clinical Trial - [link](#)

### **Thorax**

- Influence of age on clinical characteristics, pharmacological management and exacerbations in children with asthma - [link](#)

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## WEBINARS & PODCASTS

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### Australian Prescriber Podcasts

- [Episode 153](#) – Blood glucose monitoring devices
- [Episode 154](#) – An update on wound management
- [Episode 155](#) – Digital health and prescribing

### MJA Podcasts

- The importance of medical record management - [link](#)

### Purple Pen Podcast

- [PPP156](#) - Cholesterol Update – link

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## UPCOMING EVENTS

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### AHHA

- A Discussion of the National Health Reform Agreement, member-only virtual roundtable, Tuesday 20th February 12pm to 1:30pm AEDT - [link](#)

### FIP

- Advancing future pharmacy and pharmaceutical sciences: Launch of the FIP AIM academic capacity assessment tool, webinar, 24 January 2024, 14:00 - 15:30 CET - [register](#)
- Climate change and vector-borne neglected tropical diseases: Positioning pharmacy practice to drive awareness, prevention and management, webinar, 30 January 2024, 15:00 - 16:30 CET - [register](#)
- Optimising cancer care: community pharmacy strategies to support patients on oral treatment, webinar, 1 February 2024, 15:00 - 16:30 CET - [register](#)